

PATENT APPLICATION

**DENTAL APPLIANCE SEQUENCE ORDERING  
SYSTEM AND METHOD**

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## DENTAL APPLIANCE SEQUENCE ORDERING SYSTEM AND METHOD

### CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] NOT APPLICABLE

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### STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] NOT APPLICABLE

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### REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

[0003] NOT APPLICABLE

### BACKGROUND OF THE INVENTION

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#### 1. Field of the Invention

[0004] The present invention is related generally to the field of orthodontics. More particularly, the present invention is related to methods and systems for dispensing a series of orthodontic appliances in a sequence to a patient.

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[0005] Repositioning teeth for aesthetic or other reasons is accomplished conventionally by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, archwires, ligatures, and O-rings. Attaching the appliances to a patient's teeth is a tedious and time consuming enterprise requiring many meetings with the treating orthodontist. Consequently, conventional orthodontic treatment limits an orthodontist's patient capacity and makes orthodontic treatment quite expensive.

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Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult.

[0006] As a result, alternative methods and systems for repositioning teeth have been developed. For example, repositioning may be accomplished with a system comprising a

series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of at least three successive steps. Most often, the methods and systems reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The individual appliances are typically comprised of a polymeric shell having the teeth-receiving cavity formed therein, typically by molding. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments.

[0007] Typically the systems are planned and all individual appliances are fabricated at the outset of treatment. Thus, the appliances may be provided to the patient as a single package or system. The order in which the appliances are to be used can be marked by sequential numbering directly on the appliances or on tags, pouches or other items which are affixed to or which enclose each appliance so that the patient can place the appliances over his or her teeth in an order and at a frequency prescribed by the orthodontist or other treating professional. Successive appliances will be replaced when the teeth either approach (within a preselected tolerance) or have reached the target end arrangement for that stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days.

[0008] In general, it is preferable to simplify procedures for the patient to increase patient compliance and reduce patient errors in carrying out the treatment protocol.

Therefore, it is desirable to utilize a packaging or ordering system which will provide appliances to a patient in a manner which is clearly discernable to the patient the order of the appliances. In addition, such packaging or ordering system should be amenable to mid-treatment changes to the treatment protocol, possibly adding or eliminating appliances after the initial set of appliances has been produced and packaged. At least some of these objectives will be met by the methods and systems of the present invention described hereinafter.

## 2. Description of the Background Art

[0009] Tooth positioners for finishing orthodontic treatment are described by Kesling in the Am. J. Orthod. Oral. Surg. 31:297-304 (1945) and 32:285-293 (1946). The use of silicone positioners for the comprehensive orthodontic realignment of a patient's teeth is described in Warunek et al. (1989) J. Clin. Orthod. 23:694-700. Clear plastic retainers for finishing and maintaining tooth positions are commercially available from RAIN TREE ESSIX,

INC., New Orleans, Louisiana 70125, and TRU-TAIN PLASTICS, Rochester, Minnesota 55902. The manufacture of orthodontic positioners is described in U.S. Patent Nos. 5,186,623; 5,059,118; 5,055,039; 5,035,613; 4,856,991; 4,798,534; and 4,755,139.

[0010] Other publications describing the fabrication and use of dental positioners include Kleemann and Janssen (1996) J. Clin. Orthodon. **30**:673-680; Cureton (1996) J. Clin. Orthodon. **30**:390-395; Chiappone (1980) J. Clin. Orthodon. **14**:121-133; Shilliday (1971) Am. J. Orthodontics **59**:596-599; Wells (1970) Am. J. Orthodontics **58**:351-366; and Cottingham (1969) Am. J. Orthodontics **55**:23-31.

#### BRIEF SUMMARY OF THE INVENTION

[0011] The present invention provides systems and methods for providing dental appliances, particularly orthodontic appliances, to a patient wherein the patient is easily able to determine the order or sequence in which the appliances should be worn. Typically the appliances are to be worn in a particular sequence to provide desired treatment, such as a progressive movement of teeth through a variety of arrangements to a final desired arrangement.

[0012] In a first aspect of the present invention, a system of dental appliances is provided comprising a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment. Typically, each of the plurality of dental appliances comprise a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement. Exemplary embodiments of such dental appliances are described in U.S. Patent Number 5,975,893, incorporated herein by reference for all purposes. In some embodiments, each of the polymeric shells has at least one terminal tooth cavity and the indicia comprises a terminal tooth cavity of differing length in each of the polymeric shells. In other embodiments, each of the polymeric shell has a height and the indicia comprises a different height in each of the polymeric shells.

[0013] In still other embodiments, the indicia comprises one or more cutouts so that each polymeric shell has a different cutout pattern. Sometimes the cutout comprises a notch in an edge of the appliance.

[0014] In yet other embodiments, the indicia comprises a color wherein each appliance has different color. The color of the appliances may have the same hue and vary by

intensity, for example. The color may comprise a dissolvable dye. Or, the system may further comprise a wrapper removably attachable to each of the appliances, wherein each wrapper has the color.

[0015] In another aspect of the present invention, a system of packaged dental appliances is provided comprising a plurality of packages each containing a dental appliance, wherein the plurality of packages are joined in a continuous chain designating an order in which each of the dental appliances are to be worn by a patient to provide dental treatment. In some instances, the packages are each joined by a perforation wherein the packages can be separated by breaking the perforation. In other instances, the packages are joined by, for example, a heat seal. Further, the system may include a marking on a package at an end of the chain indicating the dental appliance to be worn first. Again, each of the plurality of dental appliances may comprise a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.

[0016] In a further aspect of the present invention, a system of dental appliances is provided comprising a plurality of dental appliances to be worn by a patient to provide dental treatment, and a framework, wherein each of the plurality of dental appliances are removably attached to a portion of the framework. In some embodiments, each of the plurality of dental appliances comprise a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement. Further, the system may comprise at least one marking on the framework indicating the order in which the appliances are to be worn by a patient.

[0017] In still another aspect of the present invention, method of dispensing dental appliances to a patient is provided. The method including the step of providing a plurality of packages wherein each of the packages includes a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, the plurality of package including a first package containing a first shell to be worn by the patient to reposition the teeth from the one arrangement to the successive arrangement and a second package containing a second shell to be worn by the patient to reposition the teeth from the successive arrangement to another successive arrangement. The method further including the steps of delivering the first package to the patient at a designated time through a remote delivery system, and delivering the second package to the patient at a later designated time through the remote delivery system. In most embodiments, the remote delivery system comprises a mail delivery system.

**[0018]** In another aspect of the present invention, a method is provided of dispensing dental appliances to a patient including providing a dispenser including a plurality of dental appliances, wherein each of the appliances comprises a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, the plurality of appliances including a first shell to be worn by the patient to reposition the teeth from the one arrangement to the successive arrangement and a second shell to be worn by the patient to reposition the teeth from the successive arrangement to another successive arrangement, and removing the first shell from the dispenser wherein removal of the first shell dispenses the second shell.

**[0019]** In a further aspect of the present invention, a method of dispensing dental appliances to a patient is provided including providing a dispenser including a plurality of dental appliances, wherein each of the appliances comprises a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, the plurality of appliances including a first shell to be worn by the patient to reposition the teeth from the one arrangement to the successive arrangement and a second shell to be worn by the patient to reposition the teeth from the successive arrangement to another successive arrangement. The method further includes removing the first shell from the dispenser, and actuating an actuator that subsequently dispenses the second shell. In most embodiments, the actuator comprises a lever, knob, or button.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0020]** Fig. 1 is a schematic illustration of a series of appliances dispensed in a chain.

**[0021]** Fig. 2 illustrates a series of appliances disposed on a framework.

**[0022]** Fig. 3 illustrates a series of appliances provided to a patient in a dispenser.

**[0023]** Figs. 4A-4B illustrate a change in length of a terminal tooth cavity between appliances in a series.

**[0024]** Figs. 5A-5B illustrate a change in height between appliances in a series.

**[0025]** Figs. 6A-6B illustrate the addition of cutouts in each appliance to indicate an order.

**[0026]** Figs. 7A-7C illustrate a change in color to indicate an order.

**[0027]** Fig. 8 illustrate an embodiment of a method of delivering appliances in a desired order.

[0028] Fig. 9 illustrates an appliance which includes a readable element embedded in the appliance.

[0029] Fig. 10 illustrates a series of packages 12, each having a label which includes at least one non-numeric indicia.

5 [0030] Fig. 11 illustrates a package of dental appliances of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

[0031] It may be appreciated that the orthodontic appliances may be dispensed to the patient in its entirety, in groups or individually. Providing the patient with the entire series at the outset of treatment may be desirable if the treatment plan is relatively short, the patient is particularly compliant, or it is particularly convenient, to name a few. In this case, the series should be ordered so that the patient can easily selected the next appliance in the sequence when needed. Such ordering may be designated through packaging or the appliance itself. In some situations, the patient may receive additional appliances during the treatment protocol for inclusion in the sequence and/or the patient may receive instructions to eliminate some of the original appliances from the treatment protocol. Therefore, such ordering should allow easy incorporation of additional appliances or deletion of appliances.

[0032] Alternatively, the patient may be provided with a subset of the entire series, such as the first ten appliances. In this case, the subset should be ordered so that the patient can easily selected the next appliance in the sequence when needed. Again, such ordering may be designated through packaging or the appliance itself. The patient may receive additional appliances during the use of the subset for inclusion in the sequence and/or the patient may receive instructions to eliminate some of the original appliances from the subset.

Alternatively, the next subset of appliances may differ from that which was initial determined at the outset of the treatment protocol. Therefore, such ordering should allow easy incorporation of additional appliances or deletion of appliances within or between subsets.

[0033] Further, the patient may be provided with individual appliances in the order in which they should be used. In this case, the appliances should be ordered so that the patient can easily differentiate the appliance they are receiving from the appliances already received. Again, such ordering may be designated through packaging or the appliance itself. In addition, such ordering should allow the appliances to be stored and distributed to the patient in the correct sequence with minimal attention from the orthodontic practitioner.

[0034] A variety of embodiments of ordering systems and methods will be described. In a first embodiment, a series of appliances are dispensed to the patient in a continuous chain, wherein the appliances are to be used in the sequence of the chain. An example of such a chain is schematically illustrated in Fig. 1. Here, each appliance 10 is disposed within a package 12, wherein the packages 12 are joined together in a continuous chain. In this embodiment, each package 12 is separable at a perforation 14 from the remaining packages 12 in the chain. It may be appreciated that the packages may be joined and/or are separable in any suitable manner including with the use of adhesives, heat sealing, ultrasonic welding, linkages or simply indications where to cut, break or separate, to name a few. To indicate the end of the chain in which it begin use, a marking may be located on the package 12 or on the appliance 10. For example, a colored marking 16 may be located on an end package 12a, as shown. This would indicate that a first appliance 10a is enclosed. Once the first appliance 10a has been removed from the package 12a and worn for a given amount of time, the patient may then open a next package 12b in the chain and remove a second appliance 10b for wearing. This may be repeated throughout the chain.

[0035] In another embodiment, illustrated in Fig. 2, a series of appliances 10 are disposed on a framework 20, such as a sprue. Sprues typically secure objects, such as molded objects, before their first use. The appliances 10 are secured to the framework 20 in any suitable manner. The appliances 10 are then removed from the framework 20 according to a the treatment protocol. For example, the first appliance 10a to be used may be disposed at one end of the framework 20, the second appliance 10b disposed next to the first appliance 10a, the sequence continuing along the framework 20. Alternatively or in addition, markings may be disposed on the framework 20 or the appliances 10 themselves indicating an ordering of use.

[0036] In another embodiment, illustrated in Fig. 3, a series of appliances 10 are provided to a patient in a dispenser 30. The dispenser 30 dispenses the appliances 10 in the order to be used. Each appliance 10 may be individually dispensed, as shown, or each appliance 10 may be contained in a package wherein the packages are individually dispensed. The dispenser 30 may include an actuator 32, such as a lever, button, switch, etc, so that actuation of the actuator 32 dispenses the appliance 10 or package containing the appliance 10. Alternatively, removal of an appliance 10 from the dispenser 30 may actuate dispensing of the next appliance 10. In this way, the patient is systematically dispensed appliances in a predetermined order of use.

[0037] In some situations it may be desired to specifically mark the appliances themselves. Such markings ensure that ordering of the appliances is distinguishable after removal of the appliances from any packaging and during use. For example, a portion of each appliance may be changed to indicate a sequence or order. Figs. 4A-4B illustrate a change in length of the appliance 10 by changing the length of a terminal tooth cavity 40. A terminal tooth cavity 40 is one of the last teeth in the appliance. Fig. 4A illustrates a first appliance 10a wherein a marked terminal tooth cavity 40a has a given length. Fig. 4B illustrates a second appliance 10b wherein a marked terminal tooth cavity 40b has a length which differs from the first appliance 10a. Here, the marked terminal tooth cavity 40b has a shorter length. The lengths can continue to differ throughout the sequence of appliances. Alternatively or in addition, the lengths of other terminal teeth may differ.

[0038] Figs. 5A-5B illustrate a change in the height of each appliance 10 to indicate a sequence or order. The height of the appliance 10 is the distance from the occlusal surfaces 46 to the edges 48 of the appliance 10. Fig. 5A illustrates a first appliance 10a having a given height. Fig. 5B illustrates a second appliance 10b having a height which differs from the first appliance 10a. Here, the second appliance 10b has a shorter height. The heights can continue to differ throughout the sequence of appliances indicating an order. It may be appreciated that the overall height of the appliance may differ or the height of specific portions of the appliance may differ through the sequence.

[0039] Figs. 6A-6B illustrate the addition of notches or cutouts 56 in each appliance 10 to indicate a sequence or order. The cut outs may be of any size, shape, orientation, or number forming any pattern. Further, the cut outs may be located on an edge 48 of the appliance 10 or on any surface, including an occlusal surface 46. Fig. 6A illustrates a first appliance 10a having a first cut out 56a. The first cut out 56a has a rectangular shape and is located near an edge 48. Fig. 5B illustrates a second appliance 10b having a second cut out 56b so that the cut out pattern of the first appliance 10a differs from that of the second appliance 10b. Here, the second cut out 56b also has a rectangular shape and is located near the edge 48 adjacent to the first cut out 56a. The cut out patterns can continue to differ throughout the sequence of appliances indicating an order.

[0040] Figs. 7A-7C illustrate a change in color, such as a hue, gradation of hues, shade, tint or intensity, for each appliance 10 to indicate a sequence or order. For example, the appliances 10 may appear darker or lighter in color through the series, such as ranging from

dark red to light pink or vice versa. Or, the sequence may follow the color of the rainbow, such as red, orange, yellow, green, etc. Or, the sequence may follow any other prescribed order of colors. Fig. 7A illustrates a first appliance 10a having a first color 60a. Fig. 7B illustrates a second appliance 10b having a second color 60b so that the color of the first appliance 10a differs from that of the second appliance 10b. The color changes can continue to differ throughout the sequence of appliances indicating an order. It may be appreciated that the appliances 10a, 10b may have the color over their entirety, as shown, or the appliances may be colored in some areas and not in others. Or multiple colors may be used on a single appliance, such as in stripes, blocks or various shapes. The color may be embedded in the appliance, such as with the use of a colored plastic rather than the typical clear plastic. Or, the color may be in the form of a dissolvable dye which dissolves in contact with air, such as upon removal from a package, or contact with liquid, such as when rinsed with water or placed in the patient's mouth. Alternatively, as illustrated in Fig. 7C, the color may be present in a peel-away wrapper 62. The colored wrapper 62 may be attached to the appliance 10 by lamination or other methods. In this example, the wrapper 62 covers the occlusal surfaces 46 of the appliance 10, however any portion of the appliance 10 may be covered. When the appliance 10 is to be used, the wrapper 62 is peeled away, as shown, and removed. In this way, the appliances may be ordered by color but worn in a transparent state.

[0041] Alternatively or in addition, the patient may be provided with individual appliances in the order in which they should be used. To provide such ordering while allowing the appliances to be stored and distributed to the patient in the correct sequence with minimal attention from the orthodontic practitioner, a method may be used in which the appliances are delivered by mail in a specific sequence. Fig. 8 illustrates an embodiment of such a method. As shown, the appliances 10 are individually packaged so that a first package 80 contains a first appliance, a second package 82 contains a second appliance, a third package 84 contains a third appliance, etc. The packages 80, 82, 84 are sent through the mail or any delivery system so that they are delivered to the patient P according to a desired schedule. For example, the first package 80 is delivered to the patient P at day 1, the second package 82 is delivered at day 7, the third package 84 is delivered at day 14, etc. It may be appreciated that the individual packages may alternatively be comprises of series of appliances, such as subsets of the entire series of the treatment plan. In such a case, the patient P is delivered a package of appliances 10 at each interval, wherein each package includes a series of

appliances. The series may itself also be ordered by any given system, including any of those mentioned above.

[0042] Fig. 9 illustrates one appliance 10 of a series of appliances wherein the appliance 10 includes a readable element 100 embedded in the appliance 10. Alternatively, the readable element 100 may be affixed to the appliance 10 or to a package enclosing the appliance. The readable element 100 may comprise a chip, a bar code or other element that is computer readable, including identification by wireless means, including radiofrequency (rf) identification. When a reader 102 passes over the element 100, the reader 102 translates the information into a word, symbol or other identifying feature. When translated into a word, the word may include, "first", "second", "third", or "last" to name a few. Also, the word may be in any language, including English, Spanish, French, German, Japanese, etc. The word or identifying feature may be auditory, such as a recording or generation of a spoken voice, or visual, such as a print display. Alternatively, the feature may be transmitted by tactile means, such as by vibration.

[0043] Fig. 10 illustrates a series of packages 12, each package 12 including at least one appliance 10. Affixed to or incorporated in each package 12 is a label 100. The label 100 includes at least one non-numeric indicia. For example, a first package 102 shows a label 100 having a series of numbers wherein one number is marked, in this case stamped with a colored dot 103. This indicates which appliance 10 the first package 102 contains in the treatment sequence. It may be appreciated that the number can be marked with any symbol by any method, including removing the number by erasure, punch-out or notching. It may also be appreciated that other symbols may be used other than numbers, wherein one of the symbols is marked. This is illustrated in a second package 104 which shows such a label 100. A third package 106 shows a label 100 having a series of symbols, such as shapes, in this case, triangles 120. The symbols themselves or the color, number, or arrangement may indicate which appliance 10 the third package 106 contains in the treatment series. It may be appreciated that such symbols may include stripes, as illustrated on a fourth package 108 which shows such a label 100. The stripes may be human readable or computer readable, such as a barcode.

[0044] Fig. 11 illustrates an embodiment of a package of dental appliances comprising a package 12 including a plurality of dental appliances 10 positioned in an arrangement within

the package 12 which indicates an order of usage. In this embodiment, the arrangement comprises stacking of the appliances.

5 [0045] Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications and equivalents may be used and the above description should not be taken as limiting in scope of the invention which is defined by the appended claims.